amino acid sequence comprising transforming or transfecting a

A2 cell with the vector of claim 3 so that the cell, under appropriate culture conditions, expresses a mammary gland cancer specific polypeptide.

REMARKS

Claims 1-25 are pending in the instant application. Claims 7, 8, 10-22, 24 and 25 have been withdrawn from consideration by the Examiner and subsequently canceled, without prejudice, by Applicants in this amendment. Claims 1-6, 9 and 23 have been rejected. Claims 1, 5 and 6 have been amended. Claims 2, 9 and 23 have been canceled without prejudice. No new matter has been added by these amendments.

Support for all amendments to the claims can be found in the specification. Specifically, support for the amendment to claim 1, part (b) to state that the fragments of SEQ ID NO: 1 encode a 15 to 139 amino acid sequence is provided in the specification at page 18, line 14, through page 21, line 7 and more specifically at page 19, lines 4-6. Support for the amendment to claim 1, part (c) to include percent identity which a sequence must have to SEQ ID NO:1 for stringent hybridization is provided in the specification at page 17, lines 14-16. Support for the

amendment of claims 5 and 6 to define the MSG polypeptide as mammary gland cancer specific is provided in the specification at page 3, lines 5-6 of the specification.

Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Restriction Requirement and Objection to Claim 1

The Examiner has made final the Restriction Requirement mailed February 26, 2002. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have canceled nonelected claims 7, 8, 10-22, 24 and 25, without prejudice. Further, to address the Examiner's objection to claim 1, Applicants have amended claim 1 to delete non-elected subject matter. In light of the finality of this Restriction Requirement, however, Applicants reserve the right to file a divisional application to the canceled and/or deleted subject matter.

II. Rejection of Claims 1-6, 9 and 23 under 35 U.S.C. § 112, second paragraph

Claims 1-6, 9 and 23 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention.

Specifically, the Examiner suggests that claims 1-6 and 9 are indefinite for use of the language "hybridizes under stringent conditions" in claim 1 and "hybridizes" in claim 2. The Examiner suggests that "stringent conditions" in the claim 1 and the hybridization conditions in claim 2 are not defined and the specification does not provide a standard for ascertaining the requisite degree of hybridization conditions or stringent conditions.

Applicants respectfully disagree with the Examiner since those of skill in the art would understand what it meant by both phrases when read in light of the specification and what is known in the art.

However, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 by replacing the phrase "which hybridizes under strin ıt conditions" with the percent identity which a sequence must have to SEQ ID NO:1 for stringent hybridization. Support for this amendment can be found in the specification at page 17, lines 14-16. Applicants have canceled claim 2 thus mooting this rejection as it pertains to claim 2.

Claims 5, 6, 9 and 23 are also suggested to be indefinite

for use of the abbreviated language "MSG" polypeptide. Further claims 5, 6 and 23 are suggested to be indefinite for this language because it is not clear which of the MSG polypeptides encoded by SEQ ID NO: 1-20 is referred to.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claims 5 and 6 to define the MSG polypeptide as mammary gland cancer specific in accordance with teachings in the specification at page 3, lines 5-6 of the specification. Further, Applicants have amended claim 1 so that it is now clear that the MSG polypeptides are encoded by SEQ ID NO:1, fragments thereof or sequence with 95% identity to SEQ ID NO:1.

Withdrawal of these rejections under 35 U.S.C. § 112, second paragraph is respectfully requested in light of these amendments.

III. Rejection of Claims 1-6 and 9 under 35 U.S.C. § 112, first paragraph - Written Description

The Examiner suggests that the instant specification does not contain a written description of the invention in such full, clear, concise and exact terms or in sufficient detail that one of skill in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing. While

the Examiner has acknowledged the specification to meet the written description provision of 35 U.S.C. § 112, first paragraph, for the isolated polynucleotide comprising SEQ ID NO:1, it is suggested that the written description provision is not met for the full breadth of the claims. Specifically, the Examiner suggests that the disclosure of a single species of nucleic acid does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length genes.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to delete part (c) drawn to variants of SEQ ID NO:1. Applicants have also amended part (b) of claim 1 to clarify that the fragments of SEQ ID NO: 1 encode a 15 to 139 amino acid sequence in accordance with the teachings of the specification at page 18, line 14, through page 21, line 7 and more specifically at page 19, lines 4-6. In addition, Applicants have amended part (d) of claim 1, now part (c), to be drawn to nucleic acid sequences with 95% identity to an antisense sequence of SEQ ID NO: 1 in accordance with teachings at page 17, lines 12-14 of the instant application.

Applicants believe that these amendments, which are clearly supported by the specification, set forth definitive structural

features of the claimed polynucleotides so that one of skill in the art can predictably identify the encompassed molecules as being identical to those now claimed. Further, the claims as amended describe distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention. See MPEP § 2163.02. Thus, the claims as amended meet the written description requirements of 35 U.S.C. § 112, first paragraph.

Withdrawal of this rejection is therefore respectfully requested.

IV. Rejection of Claims under 35 U.S.C. § 112, first paragraph

Claim 23 has been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification is such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is respectfully pointed out, however, that claim 23 has been canceled, thus mooting this rejection.

Claims 1-6 and 9 have also been rejected under 35 U.S.C. § 112, first paragraph. The Examiner has acknowledged the specification to be enabling for SEQ ID NO:1. However, the

Examiner suggests that the specification does not reasonably provide enablement for a nucleic acid sequence which "encodes" the same proteins as that encoded by SEQ ID NO:1.

It is respectfully pointed, however, that the pending claims have been amended and no longer include any reference to nucleic acid sequences which encode a protein. Accordingly, this rejection is also now moot.

Claims 1-6 and 9 have also been rejected under 35 U.S.C. § 112, first paragraph, as the Examiner suggests that the specification does not reasonably provide enablement for a nucleic acid sequence which "hybridizes under stringent conditions" to an antisense of SEQ ID NO:1, a polynucleotide "comprising a fragment" of SEQ ID NO:1 and an antisense oligonucleotide which "hybridizes" to SEQ ID NO:1.

It is respectfully pointed out, however, that the claims as amended are no longer drawn to nucleic acid sequences which "hybridize under stringent conditions" or antisense oligonucleotides which "hybridize" to SEQ ID NO:1, thus mooting this rejection as it pertains to these phrases.

Further, with respect to fragments of SEQ ID NO:1, the claims have been amended in accordance with the teachings at page 18, line 14, through page 21, line 7, to specify that the

fragment of a nucleic acid sequence of SEQ ID NO: 1 encodes a 15 to 139 amino acid sequence. Applicants believe that the teachings of the specification at page 18 through 21 regarding fragments are adequate to enable one of skill in the art to make and use the fragments as now claimed.

Claims 5 and 6 have also been rejected under 35 U.S.C. § 112, first paragraph. The Examiner has acknowledged the specification to be enabling for a method of producing a MSG polypeptide recombinantly encoded by SEQ ID NO:1 or a cell expressing a MSG polypeptide recombinantly encoded by SEQ ID NO:1. However, the Examiner suggests that the specification does not reasonably provide enablement for a method for producing "any" MSG polypeptide or a cells expressing "any" MSG polypeptide. Accordingly in an earnest effort to advance the prosecution of this case, Applicants have amended claims 5 and 6 to specify that the MSG polypeptide is recombinantly encoded by a nucleic acid sequence comprising SEQ ID NO:1 or a fragment of a nucleic acid sequence of SEQ ID NO: 1 encoding a 15 to 139 amino acid sequence.

Withdrawal of these rejections under 35 U.S.C. § 112, first paragraph for lack of enablement is respectfully requested in light of the above arguments and the amendments to the claims.

V. Rejection of Claims 1, 2 and 9 under 35 U.S.C. § 102(b)

Claims 1, 2 and 9 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,837,468. The Examiner suggests that U.S. Patent 5,837,468 teaches a sequence which is 100% similar to SEQ ID NO:1 over a length of 16 nucleotides from nucleotide 764 to 780. The Examiner suggests that this sequence would hybridize under stringent conditions to an antisense sequence of SEQ ID NO:1 or is a polynucleotide comprising a fragment of at least 15 contiguous nucleobases of SEQ ID NO:1.

Applicants respectfully traverse this rejection.

At the outset, it is respectfully pointed that claim 9 has been canceled. Further claim 1 has been amended and is now drawn to an isolated polynucleotide comprising SEQ ID NO: 1; a fragment of SEQ ID NO: 1 encoding a 15 to 139 amino acid sequence; or a nucleic acid sequence with 95% identity to an antisense sequence of SEQ ID NO: 1. Thus, U.S. Patent 5,837,468 which teaches a nucleotide sequence with only a 16 nucleotide overlap with SEQ ID NO:1 does not teach all the elements of the claims as amended. Therefore, in accordance with MPEP § 2131, this

reference cannot anticipate the claims as amended.

Withdrawal of this rejection is therefore respectfully requested.

VI. Rejection of Claims 3-6 under 35 U.S.C. § 103(a)

Claims 3-6 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,837,468, in view of U.S. Patent 4,889,806 and Sambrook et al. 1989 (Molecular Cloning, A Laboratory Manual, 2nd Edition, Cold Spring Harbor Press, Cold Spring Harbor, p 16.3-16.4). The Examiner suggests that it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the polynucleotide of U.S. Patent 5,837,468 with the methods of Sambrook et al. and U.S. Patent 4,889,806 because U.S. Patent 4,889,806 specifically teaches that it is conventional to transfer genetic materials into plasmids or vectors and then transfer the plasmids or vector into host cells and clonally propagate the genetic material and because Sambrook et al. teach that cloned genes are conventionally expressed using expression vectors. Further, the Examiner suggests that one of ordinary skill in the art at the time the invention was made would have been motivated to combine the polynucleotide or U.S. Patent 5,837,468 with the methods of

Sambrook et al. and U.S. Patent 4,889,806 because Sambrook et al. specifically teach multiple uses for expressed cloned proteins.

Applicants respectfully traverse this rejection.

Claims 3-6 are dependent claims ultimately depending from claim 1. In accordance with MPEP § 2143.03, if an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious.

The cited combination of references fail to provide the requisite teaching or suggestion in accordance with MPEP § 2143 to render obvious a claim drawn to an isolated polynucleotide comprising SEQ ID NO: 1; a fragment of SEQ ID NO: 1 encoding a 15 to 139 amino acid sequence; or a nucleic acid sequence with 95% identity to an antisense sequence of SEQ ID NO: 1.

The teachings of U.S. Patent 5,837,468 have been discussed in detail in Section V, supra. As discussed in Section V, supra, U.S. Patent 5,837,468 does not teach the isolated polynucleotide sequences as set forth in claim 1. Nor is there any suggestion of the polynucleotide sequences of claim 1 in U.S. Patent 5,837,468.

Further, the teachings of the secondary references cited in this rejection fail to remedy the deficiencies of the primary reference.

U.S. Patent 4,889,806 discloses a DNA cloning system based upon yeast artificial chromosomes which allows the cloning of large segments of greater than 50 kb of exogenous DNA. No specific polynucleotide sequence as claimed in the instant application are taught or suggested in this reference.

Sambrook et al. is a reference text used by those skilled in the art for its general teachings on methodologies for molecular cloning. This reference also fails to provide any teaching or suggestion of the specific polynucleotide sequences as claimed.

Accordingly, since this combination of cited references does not teach or suggest all of the limitation of the invention as claimed, it cannot render obvious the instant invention.

Withdrawal of this rejection under 35 U.S.C. § 103(a) is therefore respectfully requested.

VII. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with Markings to Show Changes Made."

Respectfully submitted,

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Date: **November 5, 2002**

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Please cancel claims 2, 7, 8, 9, and 10-25, without prejudice.

Please amend the claims as follows:

1. (amended) An isolated polynucleotide comprising:

(a) SEQ ID NO: 1~~, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19 or 20~~;

(b) a fragment of ~~at least 15 contiguous nucleobases of~~ SEQ ID NO: 1 ~~, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19 or 20,~~ encoding a 15 to 139 amino acid sequence;

~~(c) a nucleic acid sequence which, due to degeneracy in genetic coding, comprises variations in nucleotide sequence as compared to SEQ ID NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19 or 20, but which still encodes the same protein~~; or

~~(d)~~ (c) a nucleic acid sequence ~~which hybridizes under stringent conditions to~~ with 95% identity to an antisense sequence of SEQ ID NO: 1~~, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19 or 20~~.

5. (amended) A method for producing a ~~MSG~~ mammary gland

cancer specific polypeptide recombinantly encoded by a nucleic acid sequence comprising SEQ ID NO:1 or a fragment of a nucleic acid sequence of SEQ ID NO: 1 encoding a 15 to 139 amino acid sequence comprising culturing the host cell of claim 4 under conditions which promote expression of the ~~polynucleotide~~ nucleic acid sequence and isolating polypeptide expressed in the cells.

6. (amended) A method for producing a cell expressing a ~~MSG~~ mammary gland cancer specific polypeptide recombinantly encoded by a nucleic acid sequence comprising SEQ ID NO:1 or a fragment of a nucleic acid sequence of SEQ ID NO: 1 encoding a 15 to 139 amino acid sequence comprising transforming or transfecting a cell with the vector of claim 3 so that the cell, under appropriate culture conditions, expresses a ~~MSG~~ mammary gland cancer specific polypeptide.